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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA SOUTHERN DIVISION

DORIS PACE LOEWEN, and KENNETH LOEWEN, Plaintiffs, vs. WYETH, INC., et al., Defendants.	)	CV 03-J-2166-S LEAD
GINGER WRIGHT, Plaintiff, vs. WYETH, INC., Defendant.	)	CV 03-J-3240-S CONSOLIDATED
MARY EDDINGS, et al., Plaintiffs, vs. WYETH PHARMACEUTICALS, INC., et al., Defendants.	)	CV 04-J-1419-S CONSOLIDATED
ELIZABETH ADERHOLD, Plaintiff, vs. WYETH PHARMACEUTICALS, INC., et al., Defendants.	)	CV 04-J-1888-S CONSOLIDATED

MEMORANDUM OPINION

This case comes before the court on the plaintiffs' motion to exclude "any" defense experts offering "[t]estimony/evidence . . . not supported by a reliable methodology" (doc. 67), the plaintiffs' brief in support of said motion (doc. 68), the defendants' response thereto (doc. 121), and the plaintiffs' reply to defendants' response (doc. 125). Both plaintiffs and defendants also filed copious amounts of evidence in support of their respective positions. Having considered the motions, evidence and pleadings filed to date, as well as the relevant law, the court finds as follows:

PROCEDURAL BACKGROUND

This case arises from the claims brought by plaintiffs, who are women diagnosed with breast cancer while taking various hormone therapy medications developed, manufactured, and marketed by the defendants. Amended Complaint (doc. 26), at ¶¶ 2-5, 158. Plaintiffs assert, in essence, that the medications they took caused them to develop breast cancer, and that defendants knew or should have known about the increased risk of cancer that the use of these medications entailed. *See id.* at ¶¶ 101-112. Plaintiffs assert various causes of action against defendants accordingly. *See id.* at ¶¶ 101-168. Defendants deny plaintiffs' claims. The experts' fields of expertise range, *inter alia*, from breast cancer causation and treatment generally (*see* Exhibit 7

of Plaintiffs' Brief, report of Dr. Lucio Miele, doc. 68)[1] to prescription drug marketing (*see* Exhibit 6 of Plaintiffs' Brief, report of Michael Mazis, doc. 68) to the Food and Drug Administration's regulatory and drug-approval process and procedures (*see* Exhibit 8 to Plaintiffs' Brief, report of Dr. Carl Peck, doc. 68, *and* Exhibit 11 to Plaintiff's Brief, report of Dr. Heidi Jolson, doc. 68). Plaintiffs filed the current motion moving the court to disallow all "[t]estimony/evidence from any of the Defense experts that are [sic] not supported by a reliable methodology" (doc. 67) and a supporting brief (doc. 68). Plaintiffs assert that none of the defense experts meets the reliability requirements established by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), because "(1) [the experts] have no methodology that supports their opinions; and/or (2) [the experts] do not have a reliable basis for their opinions; and/or (3) [the experts'] opinions on causation directly contradict Wyeth's own position of a fact Wyeth's lawyers admit–unopposed estrogen use causes endometrial cancer." Plaintiffs' Brief (doc. 68), at 3. Defendants filed a response requesting the court to deny the plaintiffs' motion in its entirety (doc. 121). The plaintiffs filed a reply to the defendants' response (doc. 125).

STANDARD OF REVIEW

Federal Rule of Evidence 702, as construed by the United States Supreme Court

[1] The Exhibits to plaintiffs' motion are all filed as doc. 102.

in *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993), requires expert scientific evidence to be both reliable and relevant, such that it appropriately assists the trier of fact. *See e.g., United States v. Henderson*, 409 F.3d 1293, 1302 (11th Cir. 2005). Rule 702 requires that such evidence or testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert*, 509 U.S. at 590. The Rule, in respect to all such matters, "establishes a standard of evidentiary reliability." *Id.* It "requires a valid . . . connection to the pertinent inquiry as a precondition to admissibility." *Id*. at 592. Where such testimony's factual basis, data, principles, methods, or their application are called sufficiently into question, the trial judge must determine whether the testimony has "a reliable basis in the knowledge and experience of [the relevant] discipline." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999) (citing *Daubert*, 509 U.S. at 592). Simply put, the evidence must be relevant to issues in the case.

Faced with a proffer of expert scientific testimony, the trial judge must determine at the outset whether the expert is proposing to testify to (1) scientific knowledge (2) that will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. *Daubert*, 509 U.S. at 592-593. This primary assessment required by courts has become known as a

"gatekeeping function" in which the court should admit testimony only if it is reliable and relevant. *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005).

"The burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion . . . ." *U.S. v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004). Because the defendants' experts' methodology is challenged by the current motion, the burden falls to the defendants to establish that their experts' testimony will be reliable. To make this determination, the court must consider whether (1) the expert is qualified to testify competently regarding the matter he intends to address; (2) the methodology through which the expert reached his conclusion is sufficiently reliable as determined by the inquiries mandated by *Daubert;* and (3) the testimony will assist the trier of fact, through the application of scientific expertise, to understand the evidence or determine a fact in issue. *See United States v. Douglas*, 489 F.3d 1117, 1124-25 (11th Cir. 2007). Even given these considerations, the inquiry required by *Daubert* is meant to be a "flexible one," and expert testimony which does not meet all or most of the *Daubert* factors may still be admissible based on the specific facts of a particular case. *United States v. Brown*, 415 F.3d 1257, 1267-68 (11th Cir. 2005).

> Our emphasis on the word "may" thus reflects *Daubert*'s description of the Rule 702 inquiry as "a flexible one." 509 U.S. at 594. *Daubert* makes clear that the factors it mentions do not constitute a "definitive checklist or test." *Id*. at 593. And *Daubert* adds that the gatekeeping inquiry must be "'tied to the facts' of a particular 'case.'" *Id*. at 591 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3rd Cir. 1985)).

Kumho Tire, 526 U.S. at 150.

In determining the reliability of a particular scientific expert opinion, the court must consider, to the extent possible, "(1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003) (citing *McCorvey v. Baxter Healthcare Corp*., 298 F.3d 1253, 1256 (11th Cir. 2002)). "Notably, however, these factors do not exhaust the universe of considerations that may bear on the reliability of a given expert opinion, and a federal court should consider any additional factors that may advance its Rule 702 analysis." *Id*. (citing *Kumho Tire Co.*, 526 U.S. at 150).

The court's focus is solely on the principles and methodology, not on the conclusions they generate. Therefore, whether the proposed testimony is scientifically correct is not a consideration for this court, but only whether or not the expert's testimony, based on scientific principles and methodology, is reliable. *Allison v. McGhan Medical Corp*., 184 F.3d 1200, 1312 (11th Cir. 1999). A "district court's gatekeeper role under *Daubert* 'is not intended to supplant the adversary system or the role of the jury.'" *Maiz v. Virani,* 253 F.3d 641, 666 (11th Cir. 2001) (quoting *Allison*, 184 F.3d at 1311). "[V]igorous cross-examination, presentation of contrary evidence,

and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Allison*, 184 F.3d at 1311 (quoting *Daubert*, 509 U.S. at 596). The correctness of an expert's conclusions is thus left to the trier of fact to determine. *See, e.g.*, *U.S. v. Brown*, 415 F.3d 1257, 1267 (2005) (citing *U.S. v. Copeland*, 20 F.3d 412, 413 (11th Cir. 1994)). Accordingly, a district court may not exclude an expert because it believes one expert is more persuasive than another expert. *See Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1293 (11th Cir. 2005). In evaluating the reliability of an expert's methods, however, a district court may properly consider whether the expert's methodology has been contrived to reach a particular result. *Id.* (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (affirming exclusion of testimony where the methodology was called into question because an "analytical gap" existed "between the data and the opinion proffered")). Likewise, "nothing in either *Daubert* or the Federal Rules of Evidences requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.

LEGAL ANALYSIS

In their motion, plaintiffs, while conceding that defendants' experts are "qualified based upon training and experience," assert that defendants have not met their burden of demonstrating that the experts' opinions are "reliable," as required by *Daubert*, because the experts "have not attempted to explain how their experience

leads to their conclusion [sic], why their experience is sufficient and how their experience was reliably applied to the facts. Instead, as doctors, they are asking the Court to take their word for it." Plaintiffs' Brief in Support of *Daubert* Motion (doc. 68), at 5-6. In short, plaintiffs allege, "Wyeth has failed to produce any proof of the methodology supporting the opinions that are being offered that Prempro does not generally cause breast cancer." *Id.* at 8. Plaintiffs raise three separate allegations against the methodology employed by defendants' experts, which shall be addressed in turn.

A. Introductory Allegations

In the Introduction of their motion, plaintiffs move this court simply to exclude no less than seventeen of the defendants' experts; however, only eight of these experts are specifically mentioned again in the motion. Drs. Allen, Arias, Levy, Mazis, Meile, Peck, Rarick, Langer, and Jolson are referenced only in the Introduction, and plaintiffs provide no specific arguments and cite no specific support justifying their allegations that these experts' testimony should be excluded.[2] While it is true, as noted *supra*, that "[t]he burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion," *U.S. v. Frazier*, 387 F.3d 1244, 1260 (11th Cir.

[2] The entirety of plaintiffs' argument with respect to these nine experts consists of assertions that "(1) [the experts] have no methodology that supports their opinions; and/or (2) [the experts] do not have a reliable basis for their opinions; and/or (3) [the experts'] opinions on causation directly contradict Wyeth's own position of a fact Wyeth's lawyers admit–unopposed estrogen use causes endometrial cancer." Plaintiffs' Brief (doc. 68), at 3.

2004), plaintiffs' broad, general assertions with respect to the insufficiency of these experts' testimony lack any specific grounds upon which the court could find that this testimony should be excluded. Absent specific allegations calling into question the sufficiency of their testimony under *Daubert*, the court is of the opinion that the nine experts referenced only in the Introduction will be permitted to testify on issues of generic and case-specific causation.[3] Plaintiffs' motion to exclude is **DENIED** as to these nine experts.

B. Expert Methodology

Plaintiffs next attack the methodology employed by defendants' remaining experts. Plaintiff's Brief (doc. 68), at 8. Plaintiffs raise three separate issues, namely (1) there is "no methodology that supports their opinions," (2) the experts "do not have a reliable basis" for their opinions, and (3) Wyeth's experts "disagree with Wyeth" and with established medical evidence. *Id.* at 3. The court shall address each of these contentions in turn.

I. "Evidence-based medicine" is not a methodology.

Plaintiffs attack defendants' experts' methodology of "evidence-based medicine" on the grounds that it "is nothing more than a mantra to be recited in response to an inquiry about methodology." Plaintiff's Brief (doc. 68), at 9-10.

[3] The allegations with respect to the remaining eight experts will be addressed individually below.

Plaintiffs further note that defendants link to the University of Oxford's website for the "Centre for Evidence Based Medicine," which plaintiffs contend provides appraisal worksheets "to be used in critical appraisal of medical evidence," and assert both that "none of Wyeth's experts appear to have such worksheets or other documents demonstrating that they did anything more than reading the literature" and that "Wyeth has not produced a single worksheet or any other document that demonstrate [sic] that any expert employed the 'evidence based medicine' reviews set forth in the very websites that Wyeth relies upon for this argument." *Id.* In their reply to defendants' response, plaintiffs again assert this complaint, noting that *Daubert* "require[s] that the [expert] opinion should be 'supported by appropriate validation–i.e., 'good grounds,' based on what is known," and protesting that they "are entitled to learn the 'good grounds' and the basis of 'scientific knowledge' on which these experts rely as support for their opinions." Plaintiffs' Reply in Support of Plaintiffs' *Daubert* Motion (doc. 125), at 3-4 (quoting *Daubert*, 509 U.S. at 590).

The court disagrees with plaintiffs' line of reasoning, which proceeds as follows: first, "evidence-based medicine" is not a methodology; second, it is instead a process of "review[]" that involves "critical appraisal of medical evidence"; and third, regardless the distinction between "review" and "methodology," defendants' experts must not have conducted such "review" because they did not provide worksheets documenting that such review was undertaken, such that plaintiffs thus

have no knowledge of the "good grounds" upon which the experts base their opinions. "Methodology" is defined as both "a body of methods, procedures, working concepts, rules, and postulates employed by a science, art, or discipline" and "the processes, techniques, or approaches employed in the solution of a problem or in doing something." *Webster's Third New International Dictionary* 1423 (1993). Similarly, "evidence-based medicine" requires both that there be evidence to support a medical hypothesis regarding a substance/disease relationship and that such evidence be evaluated objectively before a conclusion can be drawn. *See* Plaintiffs' Brief (doc. 68), at 8-9; Defendants' Response to Plaintiffs' *Daubert* Motion (doc 121), at 8. Here, if the "problem" in question is whether hormone replacement therapy causes breast cancer, and one "body of methods" or "process" that the defendants' experts use to reach a "solution" thereto is to review objectively the available medical literature published and studies conducted pertaining to this "problem," the court is hard-pressed to surmise that despite these evaluative steps, "no methodology" exists.[4]

Neither the strength of this particular methodology, either in isolation or vis-à-vis alternative methodologies, nor the accordant weight attached thereto is a decision to be made by the court; these determinations are best left for the finder of fact. Again,

[4] Or, as one of defendants' experts, Dr. Chodosh, observes: "[M]y methodology is to evaluate the scientific literature, the medical literature, to rely upon my training and experience as a scientist and a physician to reach a conclusion, . . . which is basically I believe the methodology that one would use to address essentially any problem in biology or medicine." Plaintiff's Brief (doc. 68), Exhibit 27, at 29:9-18.

"vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Allison v. McGhan Medical Corp*., 184 F.3d 1200, 1311 (11th Cir. 1999). The court agrees with defendants, however, that "[s]imply because Defendants' experts did not provide worksheets regarding their review of the literature and the formulation of their opinions does not mean Defendants' experts did not employ a methodology." Defendants' Response (doc. 121), at 9. To the limited extent that "evidence-based medicine" as a methodology overcomes the burdens which must be surmounted for admission at trial, it is sound.[5] Likewise, the testimony of those experts whose opinions are specifically challenged because they are grounded in this methodology[6]–Drs. Rubin, Blackwell, Ley, Acs, and Chodosh–is not inadmissible on these grounds.

II. Defendants' experts offer "no reliable basis" for their opinions.

Plaintiffs next allege that "Wyeth's experts . . . provide conclusory statements that do not identify the factual basis supporting the statements," especially when

[5] The court also notes, as defendants observe, that "evidence-based medicine is . . . supported by the foremost American public health institutions" including the American Diabetes Association, the United States Food and Drug Administration, and the National Medical Association (*see* Defendants' Response (doc. 121), at 8-9), and, in the words of one of the experts, is "taught in every graduate and medical school in the country" (*see* Plaintiff's Brief (doc. 68), Exhibit 24, Deposition of Dr. Richard Blackwell, May 2, 2011, at 67:16-18).

[6] *See* Plaintiffs' Brief (doc. 68), at 11.

compared with those statements provided by plaintiffs' own experts, and cite several specific examples from various experts' testimony. Plaintiffs' Brief (doc. 68), at 12. Defendants counter that their experts' methods are reliable under Rule 702 and *Daubert* because "[r]eviewing the literature is a scientifically reliable means of reaching a general causation opinion . . . *as long as the expert reliably interprets the scientific literature*," and "one means of showing that testimony is based on 'scientifically valid principles' is 'by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication.'" Defendants' Response (doc. 121), at 9-10 (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.2d 1311, 1317-1318 (9th Cir. 1995) (emphasis in original)). Each of plaintiffs' specific allegations will be addressed in turn.

A. Allegations against Dr. Chodosh

Plaintiffs allege that in his report, Dr. Chodosh "provide[s] conclusory statements that do not identify [either] the factual basis supporting the statements . . . [or] any medical literature that supports the statements," and lament that "[t]here is no possible way for Plaintiffs or this Court to examine the validity of these statements due to this failure." Plaintiffs' Brief (doc. 68), at 12. Specifically, they quote one sentence of Dr. Chodosh's report, in which he critiques the report by plaintiffs' expert Dr. Naftalis, and allege that Dr. Chodosh "fails to identify any medical literature that

supports the statements contained in this opinion," as opposed to Dr. Naftalis, who plaintiffs allege "provides a detailed description of her opinions and factual documentation that supports each of her conclusions." *Id.* at 11-12 (citing Plaintiffs' Exhibit 16, at 1).

Plaintiffs' discussion of "factual documentation" appears to refer to the fact that Dr. Naftalis's report includes footnotes providing citations referencing specific articles. While Dr. Chodosh's report does not contain footnotes, it does include a twenty-three page reference list of 358 sources which Dr. Chodosh has consulted in forming his professional opinion. *See* Plaintiffs' Brief (doc. 68), Exhibit 16, "Exhibit B Reference List." This is compared to Dr. Naftalis's own reference list, which contains 153 sources, including some authored by Dr. Chodosh himself. *See* Plaintiffs' Brief (doc. 68), Exhibit 28. While it may be easier for the lay individual to read and comprehend the direct sourcing of Dr. Naftalis's report, the court certainly does not interpret the omission of footnotes in Dr. Chodosh's report as indicative of any "fail[ure] to identify any medical literature that supports the statements contained in []his opinion." Moreover, in response to plaintiffs' complaint that "[t]here is no possible way . . . to examine the validity of these statements," the court agrees with defendants that "[p]laintiffs had the opportunity . . . to determine this information by asking him during his deposition or by reviewing the literature on the list he

provided." Defendants' Response (doc. 121), at 11.[7]

For these reasons, Dr. Chodosh's testimony will not be denied admission at trial on these grounds.

B. Allegations against Drs. Chodosh, Acs, and Dunton

Plaintiffs next allege that "[w]hen questioned during depositions, Wyeth's experts either could not or would not identify specific medical literature that supported their opinions," making specific reference to the testimony of Drs. Chodosh, Acs, and Dunton. Plaintiffs' Brief (doc. 68), at 12-15.

With respect to Dr. Chodosh, plaintiffs' allegations are simply incorrect. When asked, "You said that there are many publications which state that there's no relationship between symptoms and breast cancer risk. Can you identify any of those publications?", Dr. Chodosh identified five articles. *Id.* at 12-13. To the follow-up question, "Can you identify any other articles which state . . . that menopausal symptoms are not related to breast cancer risk?", Dr. Chodosh indicated that he "would need [his] stack of papers to go through to find those statements" because such statements are "common accepted fact and recognition in clinical medicine" and thus "wouldn't stand out in [his] mind because they're consistent with everything we know." *Id.* at 13-14. Dr. Chodosh did not, as plaintiffs assert, refuse to identify, or

[7] The court notes that these conclusions also apply to other experts against whom plaintiffs levy this criticism–specifically, Dr. Rubin and Dr. Ley. *See* Plaintiffs' Reply (doc. 129), at 4-9.

manifest an inability to identify, the literature in question; instead, he identified five articles in response to one question and indicated a willingness, given time, to identify more in response to the follow-up question. The court sees no reason not to allow his testimony into evidence on these grounds.

With respect to Dr. Acs, who provided a reference list of 85 academic articles in his report (*see* Plaintiffs' Brief (doc. 68), Exhibit 12), plaintiffs allege that he "could not identify articles that supported his understanding about the effect of hormone therapy on breast tissue." Plaintiffs' Brief (doc. 68), at 14. This allegation stems from the following exchange, as quoted by plaintiffs:

> Q [from plaintiffs' attorney]: Where have you gotten your understanding on your background knowledge about the effect of hormone therapy on breast tissue?
> A [by Dr. Acs]: From the literature.
> Q: What specific literature?
> A: Well, I can't give you any specific literature. I read an average of five papers a day, so I can't possibly give you any specific article on those.
> Q: Do you recognize that hormone therapy with estrogen plus progestin increases the risk of breast cancer?
> A: There are some epidemiological studies that have shown an increased risk in postmenopausal women taking hormone-replacement therapy. I have to add that the risk is minimal at most, while other studies show no risk or actually there are studies that show a decreased risk.
> Q: Are you able to name those studies for me?
> A: No, I don't [sic]. There are many.

Id. (quoting Plaintiffs' Exhibit 30, Deposition of Dr. Geza Acs, June 12, 2006, at

52:14-53:9).

Plaintiffs' characterization of Dr. Acs's testimony as evincing an inability to identify the relevant articles is inaccurate. In the testimony immediately following the excerpt quoted above, the following exchange took place:

> Q: Do you intend to rely on any specific studies for your testimony . . . ?
> A: I will if I'm asked to.
> Q: Anything beyond what you have listed in your report or what has been provided to me before today?
> A: No.

Plaintiffs' Brief (doc. 68), Plaintiffs' Exhibit 30, Deposition of Dr. Geza Acs, June 12, 2006, at 53:10-16. This excerpt reveals that Dr. Acs was at worst unwilling to review the reference list he provided in order to indicate what specific articles led to what specific conclusions. This is supported by his testimony, quoted above, that he would not be relying on any sources other than what he listed in his report. Again, as noted earlier with respect to another expert, "[p]laintiffs had the opportunity . . . to determine this information by . . . reviewing the literature on the list [Dr. Acs] provided." Defendants' Response (doc. 121), at 11. This testimony is not inadmissible on the grounds upon which it is challenged.

Plaintiffs next allege that Dr. Dunton "flat out refused to identify articles that supported one of his conclusions." Plaintiff's Brief (doc. 68), at 14. This allegation

stems from the following exchange:

> Q [from plaintiffs' attorney]: And what – what studies have you looked at that leads [sic] you to believe that oral micronized progesterone is not safer?
> A [from Dr. Dunton]: Well, there are several studies in the literature that look at that and they don't seem to show me that they are a safer alternative than other hormone therapy preparations.
> Q: And which studies would those be?
> A: I'd have to go through my reference list to identify those. And I don't have it in front of me right now.
> Q: Is it not part of your reports attached as exhibit three and four?
> A: I didn't attach it, I'm sorry.
> Q: So sitting here today, you can't identify even one study that led you to conclude that oral micronized progesterone is not safer; is that right?
> A: That is not safer?
> Q: It is not safer than progestin, than MPA?
> A: No, I can – I'm not going to give you a study off the top of my head. I'm telling you that those studies exist and I've read that, but it does not – that is not a safer alternative.

Id. at 14. Plaintiffs excerpt this exchange as evidence supporting their allegation that Dr. Dunton's testimony is inadmissible because "*Daubert* requires more than just the expert's personal opinions. The opinions must have a reliable basis that can be examined by the Court to ensure the opinions pass *Daubert* muster." *Id.*

Yet again, plaintiffs mischaracterize the expert's testimony as mere opinion. Dr. Dunton did not "refuse[] to identify articles that supported one of his conclusions," as plaintiffs contend; instead, he plainly stated to plaintiffs' counsel that such articles

existed, he had reviewed and was familiar with them, and they were included in his reference list, but that he did not have the list with him at that moment and did not wish to "give . . . a study of the top of [his] head." This statement is simply not a refusal. Dr. Dunton indicated that the source list existed and that such list contained the article or articles in question. All that plaintiffs' counsel needed to do was request that Dr. Dunton supplement his testimony with the list at a later date, or simply furnish plaintiffs with a copy of the same so that they could review the article or articles which Dr. Dunton indirectly cited. As plaintiffs' own court filings indicate, at some point prior to filing the present motion they even acquired a copy of such list. *See* Plaintiff's Brief (doc. 68), Exhibit 15, Defendant's [sic] Expert Reports of Charles Dunton, MD, re: Doris Pace Loewen and Ginger Wright, "Charles Dunton Reference List." A decision by an otherwise-qualified expert, testifying under oath, not to identify and summarize off-the-cuff the conclusions of a substantial academic article which the expert has otherwise identified in his own source list should be viewed not as a "refusal" to identify such expert's sourcing, but instead as a decision by a professional who does not wish to place misleading or inaccurate information into the record. Dr. Dunton's testimony should certainly not be deemed inadmissible under these circumstances.

In sum, as discussed above, the court cannot discern how the cited testimony of

any of Drs. Chodosh, Acs, or Dunton indicates either an inability or a refusal to identify specific literature supporting their opinions. Their testimony is not inadmissible on these grounds.

III. Wyeth's Experts Disagree with Wyeth and with Established Medical Evidence.

Plaintiffs' final allegation is that "[t]he invalidity of several of Wyeth's experts' purported methodology is exposed by the fact that the experts even disagrees [sic] with their own client, Wyeth, on a fact that Wyeth admits." Plaintiffs' Brief (doc. 68), at 15. However, the "fact" for which plaintiffs cite four of defendants' experts–Drs. Blackwell, Acs, Ley, and Wick–is only partially related to the "fact" which plaintiffs allege is stated by various individuals speaking on behalf of defendants. In actuality, there appear to be at least two, if not three, separate "facts" at issue here.

The first such "fact," and the one which plaintiffs allege is supported by the testimony of the four experts denoted above, is that "unopposed estrogen does not cause endometrial cancer." *Id.* at 16. Plaintiffs state that Wyeth attorney Lane Heard "admitted" to Judge Watkins of the Middle District of Alabama at a science hearing on May 24, 2011, that "[w]e know that estrogen causes endometrial cancer," and that such admission "is consistent with previous testimony by Wyeth officials." *Id.* Plaintiffs then cite numerous additional examples of instances where they allege

defendants' experts have contradicted either Wyeth's attorneys or Wyeth representatives on this "fact." *See id.* at 16-18. The second "fact"–which plaintiffs' brief intermingles and conflates with the first, and which is arguably actually two "facts"–comes from testimony by several Wyeth representatives that estrogen hormones will cause breast cancer cells either to grow bigger or to proliferate. *See* Plaintiffs' Brief (doc. 68), at 16 n.55-63 and accompanying text. Ultimately, plaintiffs assert an inconsistency between the "facts" stated in the testimony of the four experts denoted above and the "facts" as stated by various representatives of Wyeth. Plaintiffs allege that this inconsistency is evidence that "[t]he inability of some of Wyeth's experts to agree with Wyeth is likely based upon the fact that the experts, at best, are unaware of or, at worst, deliberately ignore studies on particular issues which are relevant to their 'opinions.'" *Id.* at 17-18.

Plaintiffs allege that Drs. Blackwell, Acs, Ley, and Wick all testified, in effect, that unopposed estrogen does not cause endometrial cancer. With the exception of Dr. Blackwell,[8] however, defendants are correct that plaintiffs "have over-simplified and

[8] Defendants argue that Dr. Blackwell "indicated that estrogen causes the endometrium to grow, which can then accumulate structural damage, but that there is not sufficient data to determine causation." Defendants' Response (doc. 121), at 14 (quoting Deposition of Dr. Richard Blackwell in *Phillips v. Wyeth*, January 31, 2008, at 213:11-17, 214:19-215:13, 216:22-217:4). While this is accurate, Dr. Blackwell also testified explicitly both that"estrogen doesn't cause endometrial cancer" (*see* Deposition of Dr. Blackwell, at 213:4-5) and, in response to a question whether estrogen use will "cause or promote" endometrial cancer," that "there's no causation that can be drawn" because "the data just isn't there" (*see id.* at 213:15-17).

mischaracterized these experts' testimony about this issue." Defendants' Response (doc. 121), at 13-14. Dr. Acs testified that while "exposure to estrogen significantly increases the risk of endometrial cancer," he did not "know of any evidence to show that it actually causes it," and "increased risk does not equal cause." Plaintiffs' Brief (doc. 68), Exhibit 33, Testimony of Dr. Geza Acs, June 12, 2006, at 71:20-22; 72:10-13; *see also* Defendants' Response (doc. 121), Exhibit 19, Deposition of Dr. Geza Acs, January 6, 2011, at 60:11-61:6. Dr. Ley, after noting both that he was "not an authority" on endometrial cancer and that he "do[es] not treat" it, actually testified that "[c]ertainly there was an *increased* risk of endometrial cancer noted when unopposed estrogens were given for menopausal symptoms," but that this evidence alone was not sufficient "to establish a cause-and-effect relationship between those two." Plaintiffs' Brief (doc. 68), Exhibit 35, Deposition of Dr. Phillip B. Ley, May 15, 2008, at 55:12-21 (emphasis added).

With respect to Dr. Wick, plaintiffs selectively quote only a small excerpt of his testimony, where he was asked about unopposed estrogen causing endometrial cancer. The excerpt in question reads as follows:

> Q [from plaintiffs' attorney]: Do you agree that the use of unopposed estrogen for estrogen replacement in postmenopausal women can cause endometrial cancer in women that have not had a hysterectomy?
> A [from Dr. Wick]: No, I don't believe that.

Plaintiff's Brief (doc. 68), Exhibit 36, Deposition of Dr. Mark Wick in *Scharff v. Wyeth*, June 21, 2011, at 10:20-11:01. Plaintiffs assert that here Dr. Wick has testified that unopposed estrogen does not cause endometrial cancer. However, his testimony continues:

> Q: It's your opinion that the use of unopposed estrogen cannot cause endometrial cancer. Is that it?
> A: No. That's not what you said. You said, was it my opinion that it did cause it. It's not as simple as that. So my answer has to be no.
> Q: And I believe I just rephrased the question in the negative. Let me try it again. Do you believe that the use of unopposed estrogen can cause endometrial cancer?
> A: Again, your question is overly broad and really can't be answered.
> Q: Why can it not be answered?
> . . .
> A: Well, because it presupposed that the only cause of a carcinoma in question would be unopposed estrogen therapy, and that simply isn't consonant with our understanding of the biology of endometrial carcinoma.

Defendants' Response (doc. 121), Exhibit 18, Deposition of Mark Wick in *Scharff v. Wyeth*, June 21, 2011, at 11:02-23. In effect, as Dr. Wick's testimony indicates, plaintiffs over-simplified the issue, and thus he had to answer "no" to the question as asked. In no way can Dr. Wick's testimony in its full context be fairly characterized as indicating a belief on the part of Dr. Wick that "unopposed estrogen does not cause endometrial cancer," as plaintiffs allege.

To further support their contention that defendants' experts lack a reliable methodology, plaintiffs make several additional indirect allegations that do not bear out under further scrutiny. Plaintiffs cite testimony that Dr. Ley was "not aware" of alleged studies with alleged findings which plaintiffs intimate would support their positions, yet nowhere–neither during the deposition itself, nor in their brief–do plaintiffs identify such studies by name or author. *See* Plaintiffs' Brief (doc. 68), at 18; Plaintiffs' Brief, Exhibit 47, Deposition of Dr. Phillip Ley, May 20, 2011, at 57:15-58:1; 60:15-61:6; 62:12-63:23. Plaintiffs also imply a "lack of reliability" is found in Dr. Rubin's testimony both because she could not recall the specific percentage of the WH1 population which started taking E+P therapy within five years of menopause without first looking at the actual study and because she did not recall looking at specific studies regarding an increased risk of breast cancer if one's BMI is greater than thirty. *See* Plaintiffs' Brief (doc. 68), at 18; Plaintiffs' Brief, Exhibit 48, Deposition of Dr. Eva Rubin, July 8, 2011, at 63:8-17; 156:6-12. The court is hard-pressed to find indicia of lack of reliability from two isolated instances in which a medical expert did not recall specific statistics or studies off the top of her head.

Plaintiffs' final allegation pertains to Dr. Wick. Plaintiffs aver that Dr. Wick's opinion "is not only discordant on whether E+P causes breast cancer, it is discordant with virtually every other source, whether scientific, medical or even Wyeth [sic], on

whether E+P is a 'risk' factor for breast cancer." Plaintiffs' Brief (doc. 68), at 18. Plaintiffs refer to the following testimony by Dr. Wick as being "crystal clear" evidence "that he does not believe that E+P is even a risk factor for breast cancer": "[I]t really wouldn't make sense to say what I believe about E+P vis-a-vis the risk of breast cancer. I don't believe there is a risk of breast cancer, period." *Id.* at 18 (quoting Deposition of Dr. Mark Wick in *Scharff v. Wyeth*, July 21, 2011, at 62:13-17).

While Dr. Wick did testify that he "do[es not] believe there is a risk of breast cancer," he also testified that "what the epidemiological data may show is, in a sense, a separate issue." *Id.* at 17 (quoting Plaintiffs' Brief, Exhibit 18, Deposition of Dr. Mark Wick in *Scharff v. Wyeth*, July 21, 2011, at 62:7-8). This statement can be explained in light of Dr. Wick's prior testimony in another case, where, in response to the question "Would you agree . . . that E+P is a risk factor for breast cancer?", Dr. Wick explained "[i]n an epidemiological sense there is in, again, selected contexts an apparent increase in risk that is attached to the use of E+P as regards the risk of breast cancer." Defendants' Response (doc. 121), at 17 (quoting Defendants' Exhibit 25, Deposition of Dr. Mark Wick in *Briggs v. Wyeth*, June 7, 2011, at 66:12-19). Thus, as defendants clarify in their Response, here

> [p]laintiffs ... conflate 'risk' and 'cause' and mischaracterize Dr. Wick's testimony as a result. Plaintiffs argue that HT ***causes*** breast cancer through a process that they call

> promotion. Defendants and their experts disagree that HT causes breast cancer through any process, promotion or otherwise. Defendants and their experts do not contest that HT use is associated with a small, increased relative risk of being diagnosed with invasive breast cancer . . . .

Id. at 15 (emphasis in original).

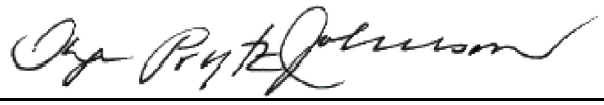
In other words, a full reading of Dr. Wick's testimony indicates that he was discussing causation as opposed to association–a distinction that the law of this jurisdiction recognizes. *See Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 n. 16 (11th Cir. 1999) ("showing association is far removed from proving causation"); *see also In re Accutane Products Liability Litigation*, 511 F. Supp. 2d 1288, 1297 (M.D. Fla. 2007), *aff'd Rand v. Hoffman-LaRoche, Inc.*, 291 Fed. Appx. 249 (11th Cir. 2008) ("[A]n association is not equivalent to causation . . . ."). Dr. Wick's testimony is thus consistent with other experts in this litigation, and does not support plaintiffs' contention that his opinions are unreliable.

CONCLUSION

For the reasons stated herein, the court is of the opinion that plaintiffs' *Daubert* motion to exclude the generic and case-specific causation testimony of Drs. Susan Allen, Raquel D. Arias, Lewis Chodosh, Barbara S. Levy, Michael Mazis, Lucio Miele, Carl Peck, Lisa D. Rarick, Robert Lagner, Heidi M. Jolson, Gaza Acs, Eva Rubin, Phillip Ley, Charles J. Dunton, Mark Wick, Gerard J. Oakley, and Richard

Blackwell is due to be denied, which the court shall do by separate order.

DONE and **ORDERED** this the 14th day of November 2011.



INGE PRYTZ JOHNSON
U.S. DISTRICT JUDGE